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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER KITE and DAVID HATTON

Appeal[1] 2008-6032
Application 10/659,413
Technology Center 1600

Decided: [2] May 1, 2009

Before, DEMETRA J. MILLS, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

STATEMENT OF CASE

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Oral hearing held April 21, 2009.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

The following claims are representative.

32. An antiseptic composition comprising at least one salt of ethylene diamine tetraacetic acid (EDTA) in solution, wherein the at least one EDTA salt comprises at least one of tri-sodium and tetra-sodium EDTA at a concentration of at least 2.0% (w/v) and less than 15% (w/v), wherein the antiseptic composition has a bactericidal effect over a broad spectrum of microbes, wherein the antiseptic composition has a pH of at least 9.5, and wherein the antiseptic composition is packaged in a sterile, non-pyrogenic form.

37. A composition of any of claims 32, 56 or 57, wherein the solution comprises less than 10% (v/v) ethanol and water.

46. A composition of any of claims 32, 56 or 57 in a pre-filled syringe.

47. A composition of any of claims 32, 56 or 57 in a single-dosage vial.

56. A lock flush composition comprising at least one salt of ethylene diamine tetraacetic acid (EDTA) in solution, wherein the at least one EDTA salt comprises at least one of tri-sodium and tetra-sodium EDTA at a concentration of at least 2.0% (w/v) and less that 15% (w/v), wherein the lock flush composition has a pH of at least 9.5, wherein the lock flush composition is packaged in a sterile, non-pyrogenic form, and wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

58. A composition of any of claims 32, 55 or 56, wherein the EDTA salt provides at least 50% of a total antimicrobial activity of the composition.

References

Wider	US 6,500,861 B1	Dec. 31, 2002
Fahim	WO 00/13656 A1	Mar. 16, 2000
Kurginski	GB 1,279,148	June 29, 1972

Remington's Pharmaceutical Sciences, 835 and 1836-1837 (7th ed., 1985).

Root et al., *Inhibitory Effect of Disodium EDTA upon the Growth of Staphylococcus epidermidis In Vitro: Relation to Infection Prophylaxis of Hickman Catheters,* 32 ANTIMICROBIAL AGENTS AND CHEMOTHERAPY no. 11, 1627-1631 (1998).

Grounds of Rejection

1. Claims 32, 34, 39, 41, 42, 45, and 55-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider.

2. Claim 46 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider and further in view Remington's Pharmaceutical Sciences.

3. Claim 47 is rejected under.35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider and further in view of Root.

4. Claims 32, 34, 37, 41, 42, 45, 55-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kurginski in view of Fahim and Wilder.

ISSUE

The Examiner argues that it would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions packaged in a sterile and pyrogen free form.

Appellants contend that they do not perceive any suggestion to combine the references in the manner proposed by the Examiner, or any motivation for doing so.

The issue is: Have Appellants shown error in the Examiner's reason to combine the cited references?

FINDINGS OF FACT

1. Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. (*See* pg. 10, 11. 10-25; and pg. 11, ll. 6- 10.) (Ans. 3.)

2. Fahim teaches that the viscosity of the composition can be adjusted by adding sodium chloride. (*See* p. 14, ll. 10-11; page 18, ll. 15-16.) The antimicrobial properties of the compositions were also reported. Fahim further teaches that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. (Fahim, page 23, Table 8, prototype 10, wherein the composition comprises 3% by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5.) (Ans. 4.)

3. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for topical application such as for cleaning skin. (*See* pg. 41, claims 35-37.) (Ans. 4.)

4. Fahim does not expressly teach that the composition is packaged in a sterile, pyrogen free form. (Ans. 4.)

5. Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials, including the surface of the body. It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. (*See* col. 1, ll. 8-20; col. 2, ll. 30-34; and col. 4, ll. 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free

form, and can be introduced into the abdominal cavity through a catheter. (*See* col. 6, ll. 9-10; col. 7, ll. 51-55.)

6. Wider teaches the compositions therein to be used for eliminating an infection on the epidermis of the body of the user where infection is encountered. (*See* abstract; col. 5, ll. 63-64.) Wider further teaches the spray application of the antimicrobial compositions therein to be used to eliminate all superficial microorganisms on the surface of the skin. (*See* col. 6, ll. 53-56.) Wider teaches that the compositions in concentrate form are diluted with pyrogen free water to form an effective use solution. *See* abstract.

7. The Examiner finds that it would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form. (Ans. 4.)

8. The Examiner finds that one of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters. (Ans. 4-5.)

9. The Examiner finds that, while the references do not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess [the] claimed properties. Since Fahim discloses the same tetrasodium EDTA as that recited in the instant

invention, the composition should possess [the] claimed properties. (Ans. 5.)

10. The Examiner finds that, while the references do not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess the claimed properties. Since Fahim discloses the same salts of EDTA as that recited in the instant invention, the composition should possess the claimed properties. (Ans. 5.)

11. In claim 56, the Examiner finds that the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes," do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The Examiner finds that if the prior art structure is capable of performing the intended use, then it meets the claim. (Ans. 5-6.)

12. Fahim does not specifically teach the antimicrobial composition in a single dosage vial. (Ans. 6.)

13. Root teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. (Ans. 6.)

14. The EDTA used by Root is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative

infections. (*See* pg. 1627, paras. 3 and 6.) Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2%). (*See* pg. 1628, ll. 18-21) (Ans. 6.)

15. The Examiner finds that it would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile condition in a single-dosage vial from the teachings of Root's polystyrene vials. (Ans. 6.)

16. Fahim fails to recite the employment of the composition in a prefilled syringe. (Ans. 6.)

17. Remington's Pharmaceutical Sciences teaches sterile, pyrogen free solutions of sodium chloride as ideal for injection. It also discloses that hypodermic syringes are used for injection of liquids. (*See* pg. 1837.) Remington also warns against injection of solutions containing pyrogens (*See* pg. 835, col. 2, para. 1), and to maintain conventional sterile methodology for injected medicaments. (Ans. 7.)

18. The Examiner finds that, possessing this teaching by Remington Pharmaceutical Sciences, the skilled artisan would have been motivated to provide a syringe filled with an EDTA solution with the expectation of using such sterile, pyrogen free solution for injection. (Ans. 7.)

19. The Specification teaches a sanitizing composition having antimicrobial and/or antifungal activity that is at least 50% of the anti-microbial and/or antifungal activity of a tri and tetra-sodium EDTA sale composition in an aqueous solution at a concentration of 4% (w/v) and at a pH of 10.5. (Original claim 22.)

PRINCIPLES OF LAW

As the Supreme Court pointed out, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Thus, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995).

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 127 S.Ct. 1727, 1731 (2007). For the same reason, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. ...[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.*

ANALYSIS

Appellants argue that the exemplary compositions, formulation methodologies and animal testing protocols described in Fahim do not disclose or suggest any sterility precautions or post formulation sterilizing procedures. (Br. 4-5.) Appellants find no uses or proposed uses of the Fahim antimicrobial handwash compositions that would suggest providing the compositions of Fahim in a sterile, non-pyrogenic form would be necessary or advisable. (Br. 5.) Applicants do not perceive any suggestion to combine the references in the manner proposed by the Examiner, or any motivation for doing so. (Br. 5.)

The Examiner argues that it would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form. (Ans. 4.)

We find no error with the Examiner's indicated motivational statement to combine the cited references. Fahim teaches antimicrobial compositions for cleaning skin comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. Wider teaches antimicrobial compositions used for eliminating infections from various surfaces, including the surface of the body are packaged in a sterile and pyrogen free form. *See* the Wider abstract, wherein it is disclosed that the compositions therein are useful for eliminating infection on the epidermis of the body; see column 6, lines 53- 55, wherein it is taught that the antimicrobial composition therein is sprayed onto skin.

We agree with the Examiner that one of ordinary skill in the art would have been motivated to prepare the antimicrobial composition of Fahim in a sterile and pyrogen free form with the expectation of success of employing the composition for eliminating infections from epidermis of the body because 1) Wider teaches antimicrobial compositions for eliminating infection on the epidermis of the body are effective when packaged in a sterile and pyrogen free form, and 2) both Fahim and Wilder teach that antimicrobial compositions therein are useful for eliminating an infection on the epidermis of the body. (Ans. 10.) "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1731 (2007). In the present case, one of ordinary skill in the art aware of the use of antimicrobials in pyrogen free form as in Wider, would have been motivated to use other antimicrobials, such as EDTA, in pyrogen free form.

Applicants argue that "the applications of Wider are contemplated for contact with skin that is not normally exposed (i.e., broken, cut skin)." (*See* pages 6-7 of the Brief.)

This argument is not persuasive. Wider teaches compositions to be used for eliminating an infection on the epidermis of the body of the user where infection is encountered. (*See* abstract; col. 5, ll. 63-64.) Wider further teaches application of the antimicrobial compositions therein to be used to eliminate all superficial microorganisms on the surface of the skin. (*See* col. 6, ll. 53-56.)

Appellants argue that "[o]ne skilled in the art would understand that Wider is not suggesting that a composition be placed in a sterile and pyrogen free form for other (non "internal spaces") purposes. Thus, Wilder does not teach or suggest the use of a composition in a "sterile and pyrogen free" form for anything but the treatment of internal spaces." (Br. 7-8.)

Again we do not find this argument persuasive. Wider teaches antimicrobial compositions for eliminating an infection on the epidermis of the body, and also teaches that the compositions therein are in sterile, pyrogen free form. (FF6.) Wider teaches that the compositions in concentrate form are diluted with pyrogen free water to form an effective use solution. (FF6.) Thus, Wilder teaches that the pyrogen free water provides the compositions therein to be effective for eliminating infection in general including the epidermis of the body.

Applicants argue that "[t]here is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with the user in a manner where packaging in a sterile, nonpyrogenic form would be beneficial." (Br. 8.)

In response, the Examiner argues that a composition for cleaning skin such as that taught by Wilder wherein the composition is sprayed onto skin for eliminating an infection on the epidermis of the body prior to surgical incision is known to be in sterile, non-pyrogenic form. (FF6.)

We find that the Examiner has established with appropriate evidence that it would have been obvious to a person of ordinary skill in the art at the time of invention to package an antimicrobial composition for cleaning skin

in a sterile, non-pyrogenic form with the expectation of employing for removing superficial microorganism from skin.

Claim 56

Appellants argue that the combination of Fahim and Wider would not result in Appellants' claimed lock flush composition. (Br. 10.) Appellants argue that there is no suggestion that any composition of Fahim would be biocompatible for use in in-dwelling catheters. (Br. 10.)

We agree with the Examiner that the intended use of the claimed composition, "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters..." does not further limit the claims and has no bearing on patentability. "[T]erms [that] merely set forth the intended use for, or a property inherent in, an otherwise old composition . . . do not differentiate the claimed composition from those known in the prior art." *In re Pearson*, 494 F.2d 1399, 1402 (CCPA 1974). "The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). *See also Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d 150, 152 81 (CCPA 1951) (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim).

We do not find that the intended use of claim 56 recites a structural limitation in the claim. We find that the one of ordinary skill in the art would have found the antimicrobial compositions of Fahim and Wider to be compatible for use in indwelling catheters. (FF5.) The obviousness rejection is affirmed.

Claims 58-59

Appellants argue that it is apparent that the EDTA salt of Fahim wound not provide at least 50% of the total antimicrobial activity of the Fahim composition. (Br. 12.)

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight tetra sodium EDTA. (*See* pgs. 37-38, claims 15-17; FF1.) Fahim teaches antimicrobial compositions for cleaning skin have a pH from about 5.0 to about 11.0. (FF1.) The Fahim compositions may comprise tetra sodium EDTA salt and can comprise other antimicrobial agents such as triclosan, PCMX, glutaraldehyde in variable amounts, wherein tetra sodium EDTA salt can be present in an amount from 0.05 to about 6.0 %. Thus, the Examiner finds that the compositions taught by Fahim broadly encompass the instantly claimed limitation wherein the antimicrobial combination composition provides at least 50% of a total antimicrobial activity of the composition because the ingredients are present in variable amounts. (Ans. 13.)

The Specification teaches a sanitizing composition having antimicrobial and/or antifungal activity that is at least 50% of the anti-microbial and/or antifungal activity of a tri and tetra-sodium EDTA sale

composition in an aqueous solution at a concentration of 4% (w/v) and at a pH of 10.5. (Original claim 22; FF19.) Because the Fahim compositions include overlapping weight ranges of EDTA at similar pH ranges, it would reasonably appear that the compositions of Fahim would similarly provide at least 50% of the antimicrobial activity. Appellants have not come forth with evidence to show that such compositions of Fahim do not provide 50% of the microbial activity. *See In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.") The obviousness rejection of claim 58 is affirmed.

2. Claim 47 is rejected under.35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider and further in view of Root.

Appellants contend that "[i]t would be absurd, unnecessary and prohibitively expensive to package the handwash composition of Fahim in a sterile condition in a single-dosage vial. Appellants submit that one of ordinary skill in the art would not be motivated by Root et al.'s use of sterile test tubes in experimental protocols to package the antimicrobial handwash composition of Fahim in a sterile, non-pyrogenic form in a single-dosage vial." (Br. 13.)

Root teaches antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2%) in sterile polystyrene test tubes (vials). (FF14.) Thus, we agree with the Examiner that Root provides motivation to package the sterile, non-pyrogenic compositions of EDTA in a single dosage vial because both Fahim and Root teach that antimicrobial compositions

comprising EDTA salts therein are useful for eliminating an infection. One of ordinary skill in the art would have been motivated at the time of invention to pack the pyrogen free, sterile antimicrobial EDTA-salt compositions in single dosage vial with the expectation of employing the compositions in experimental protocols. The ordinary practioner of ordinary creativity was aware of single use packaging, as disclosed by Root, which permits enhanced sterility and reduced risk of infection. *See, e.g., Kendall Co. v. Progressive Medical Technology, Inc.*, 85 F.3d 1570, 1572 (Fed. Cir. 1996) ("[I]n order to reduce the risk of contamination between successive patients, its customers planned to replace the pressure sleeves after each use by a single patient. Kendall did not discourage this practice and, in fact, marked 'FOR SINGLE PATIENT USE ONLY. DO NOT REUSE.'")

Appellants have not provided evidence to rebut this finding. The obviousness rejection of claim 47 is affirmed.

4. Claims 32, 34, 37, 41, 42, 45, 55-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kurginski in view of Fahim, and Wilder.

Appellants contend that the Examiner has not established a prima facie case of obviousness (Br. 15) and that while the composition of Kurginski may comprise tetra-sodium EDTA, it is improper to treat the composition of Kurginski as simply a generic composition which comprises tetrasodium EDTA. It is a toilet cleaning composition. (Br. 14.) Appellants further contend that the Examiner concedes that Kurginski does not teach its composition packaged in a sterile, non-pyrogenic form. (Br. 14, 17.)

We agree with Appellants that the Examiner has not established why one of ordinary skill in the art would have been motivated to supply a toilet cleaning composition which is not intended for use on the skin or in any sort of antiseptic environment, in a sterile, non-pyrogenic form. The obviousness rejection is reversed.

CONCLUSION

We affirm the obviousness rejections of claims 32, 34, 39, 41, 42, 45, and 55-60 under 35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider; of claim 46 under 35 U.S.C. 103(a) as being unpatentable over Fahim in view of Wider and further in view Remington's Pharmaceutical Sciences; and of claim 47 under 35 U.S.C. § 103(a) as being unpatentable over Fahim in view of Wider and further in view of Root. The obviousness rejection of claims 32, 34, 37, 41, 42, 45, 55-60 over Kurginski in view of Fahim, and Wider is reversed. In sum, claim 37 is without rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

LP

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